

APPENDIX 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Omni-Tract Surgical®
A Division of Minnesota Scientific, Inc.
1100 New Brighton Blvd.
Minneapolis, MN 55413
Telephone: (612) 623-0396

Product: Classification Name: Manual Surgical Instrument
For General Use (21 CFR 878.4800)
Common Name: Surgical Retractor System
Trade/Proprietary Name: MRI FastSystem Retractor System

**Substantially
Equivalent
Products** Omni-Tract Surgical Retractor Systems (K842762, K853947) and
other commercially distributed devices.

Description: The device is a manually adjusted, MR safe, retractor system. It is a
table mounted retractor consisting of a table rail clamp, table post,
adjustable retractor support arms and retractor frame that is adjustable
to the desired plane with respect to the surgical site.

Intended Use: The intended use is for general surgery performed in an intraoperative
MRI setting.

**Comparison
To Substantial
Equivalent
Products** Predicate devices have the same intended use (outside of the MRI
suite), principle or operation and general design. Differences between
the new and predicate devices were subjected to bench, sterilization,
biocompatibility and safety testing to demonstrate that they do not
affect safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 17 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Catherine Miller
Regulatory Affairs Manager
Omni-Tract Surgical
1100 New Brighton Boulevard
Minneapolis, Minnesota 55413-1660

Re: K001339
Trade Name: MRI FastSystem Retractor System
Regulatory Class: I
Product Code: GAD
Dated: April 19, 2000
Received: April 27, 2000

Dear Ms. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Catherine Miller

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX 1

STATEMENT OF INDICATIONS FOR USE

Omni-Tract Surgical® MRI FastSystem Retractor System

The Omni-Tract Surgical® MRI FastSystem is intended for use in abdominal surgical exposures for general, vascular, urologic, neurological, orthopedic and gynecologic surgical procedures where intraoperative MRI is being utilized.

Dan R. Kochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001339